REMARKS

CLAIMS

Claims 39-53 and 67-74 are currently pending in the application. In the Final Office Action of November 2, 2006, the Examiner rejects pending claims 39-53 and 67-74 on grounds relating to the written description requirement and anticipation. The rejections of claims 39-53 and 67-74 are traversed. Applicant responds to the Examiner's rejections as subsequently recited herein, and respectfully requests reconsideration and further examination of the present application.

A. Applicant traverses the Examiner's 35 U.S.C. § 112 rejection of pending claims 39-53 and 64-74 for purportedly failing to comply with the written description requirement.

Pursuant to MPEP § 2163 II(A):

> The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96. [Emphasis added].

Likewise, pursuant to MPEP § 2163.04:

> A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. *Werheim*, 541 F.2d at 263, 191 USPQ at 97. [Emphasis added].

In the Final Office Action of November 2, 2006, page 3, the Examiner alleges that "[n]owhere in the specification did the examiner find support for deposition of a *crystalline* film layer." Applicant respectfully disagrees with the Examiner's finding (or more appropriately, lack thereof). As acknowledged by the Examiner, page 11 line 30 – page 12 line 4 of Applicant's originally filed application describes, "When employing vacuum deposition methodologies, the crystalline structure of the deposited film affects

the mechanical properties of the deposited film." [Emphasis added]. In addition, as omitted by the Examiner, page 13 lines 6 – 9 of Applicant's originally filed application describes, "The resulting stent may then be subjected to post-deposition processing to modify the crystalline structure..." [Emphasis added].

The Examiner further argues that "nowhere does the specification disclose that these forms [amorphous, monocrystalline, nanocrystalline] are present before post treatment and during deposition." *See* Final Office Action of November 2, 2006, page 4. Applicant is baffled by this particular remark. Applicant is not claiming (and has not claimed) that the crystalline structure be amorphous (which is non-crystalline), monocrystalline (which is a single crystal, and generally understood not to be applicable to metal film biomaterials, *see, e.g.*, *Whitcher* [0039] and [0040] teaching single crystal filament or wire, not film materials), or nanocrystalline. U.S. Patent Application Publication No. 2003/0018381 (hereinafter referred to as "*Whitcher*"), the reference cited by the Examiner to form an anticipation rejection against the pending claims, however, does describe crystalline forms being amorphous, monocrystalline, and nanocrystalline. *See* claim 1 of *Whitcher*. In all likelihood, the Examiner has confused the disclosure of the pending application with that of *Whitcher*. To Applicant's best knowledge of patent law, there is no requirement, pursuant to current patent statutes or caselaw, that a pending application must have support in its specification for the claims of a prior art reference. Accordingly, the Examiner's argument that "nowhere does the specification disclose that these forms [amorphous, monocrystalline, nanocrystalline] are present before post treatment and during deposition" is illogical.

The Examiner also argues that "the specification does not support deposition of an as deposited crystalline film ... no support in the specification was found ..." Again, Applicant kindly references page 11 line 30 – page 12 line 4 of Applicant's originally filed application, which describes "When employing vacuum deposition methodologies, the crystalline structure of the deposited film affects the mechanical properties of the deposited film." [Emphasis added]. Applicant also references page 13 lines 6 – 9 of Applicant's originally filed application, which describes "The resulting stent may then be subjected to post-deposition processing to modify the crystalline structure..." [Emphasis

added]. As is clear to a reader skilled in the stent arts, Applicant discloses a vacuum deposition methodology that deposits a film in crystalline form. While the stent or resulting film may be subjected to post-deposition processing to modify the already existing crystalline film, the deposited film is nonetheless already in crystalline form. Accordingly, contrary to the Examiner's assertions, there is clear support for an "as-deposited crystalline film."

Lastly, Applicant submits that under the standard set forth by the MPEP (described above) and by the supporting caselaw pertaining to the written description requirement, the description of the pending application clearly establishes that Applicant had possession of the claimed invention, *i.e.*, deposition of a crystalline film layer, at the time the original application was filed. Thus the written description requirement is met. Moreover, as noted above, it is the Examiner who has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. Applicant submits that the Examiner's mere conclusory statements (recited above), alleging that the written description requirement is not met, lack supporting evidence and do not meet the "preponderance of evidence" standard set forth by the courts. Accordingly, the Examiner's 35 U.S.C. § 112, first paragraph rejection, for purportedly failing to comply with the written description requirement, is without merits and improper. Thus, Applicant kindly requests that the Examiner withdraw the 35 U.S.C. § 112, first paragraph rejection of claims 39-53 and 67-74.

B. Applicant traverses the Examiner's 35 U.S.C. § 102(e) rejection of pending claims 39-53 and 67-74 as being anticipated by Whitcher et al. (U.S. Patent Application Publication No. US 2003/0018381).

The claimed method (as recited in independent claims 39, 47 and 67 of the pending application) requires, *inter alia*, the step of vacuum depositing a stent-forming metal onto a substrate under process conditions selected to minimize (or substantially eliminate) formation of chemical and intra- and inter-granular precipitates in the bulk material of the as-deposited crystalline film.

With regard to the Examiner's anticipation rejection based on *Whitcher*, in the Final Office Action of November 2, 2006, the Examiner appears to maintain the position she took in the Non-Final Office Action of February 24, 2006. In fact, with the exception of the Response to Arguments section on pages 2-3 of the Final Office Action of November 2, 2006, the Examiner's arguments, relating to the scope of *Whitcher's* disclosure, appear substantially the same as that in the Non-Final Office Action of February 24, 2006. Accordingly, Applicant incorporates by reference the arguments Applicant submitted in the Response to the Non-Final Office Action of February 24, 2006. Furthermore, Applicant responds to the Examiner's "Response to Arguments".

According to the Examiner in the Final Office Action of November 2, 2006:

> Whitcher clearly discloses precisely controlling the microstructure of a metal, see P0028, P0040, further discloses minimizing precipitates (discloses filtering of impurities and isotopes during deposition, thus precipitates, P0038). Granular precipitates are a property of the microstructure. When the microstructure is controlled, as disclosed, inherently the granular precipitates are also, since they are an element of the microstructure ... What effect occurs (granular precipitates for instance) is inherently being controlled by the *selection* (that is whether there is little or a lot of precipitates changes depending on the users [sic] *selection* of the condition). "Selected to minimize" is analogous to preselected or predetermined, see 69 USPQ2d 1001, Ferguson Beauregard/Logic Controls, Division of Dover Resources Inc. v. Mega Systems LLC US Court of Appeal Federal Circuit. [Emphasis added].

Applicant respectfully disagrees with the Examiner's interpretation of *Whitcher*. Contrary to the presently pending claims, *Whitcher* broadly defines "vapor deposition" as any process of deposition metals and metal compounds by dissipating metal ions from a vaporous medium. Specifically disclosed are physical vapor deposition processes of evaporation and sputtering; additionally, direct and assisted ion beam deposition and chemical vapor deposition are suggested as being useful. *Whitcher*, however, offers no guidance or teaching that any of these process may be employed to form an as-deposited crystalline film by vacuum deposition while controlling the deposition process to minimize precipitate formation. The reference merely states the specific conditions selected, *i.e.*, chamber pressure, deposition rate, without any suggestion that those conditions may be controlled in such a manner as to minimize precipitate formation in a

crystalline film or even that a crystalline film is formed as a result of the specific selected conditions. In fact, in none of the Examples found in *Whitcher* is there any statement or suggestion either that 1) the film is crystalline or 2) that precipitate formation has, in fact, been controlled.

Relying on the *Whitcher* reference, the Examiner argues that "Whitcher discloses controlling the microcrystal structure" citing Paragraphs 0011, 0028, 0038, 0042 and 0043. Based upon these paragraphs the Examiner argues that "inherently granular precipitates are controlled, since granular precipitates are an element of a materials [sic] microstructure." A careful review of the paragraphs cited by the Examiner fails to corroborate the Examiner's conclusions.

Whitcher Paragraph 0011 states only in pertinent part: "The medical devices also have a crystallographic structure that is produced by the vapor deposition methods of the present invention. Desirable crystallographic structures include amorphous, nanocrystalline and monocrystalline structures." Apart from being internally inconsistent scientifically due to the fact that an amorphous structure is not crystalline[1], this paragraph is merely a recitation that the device may have either a nanocrystalline or monocrystalline structure. The term nanocrystalline is undefined in *Whitcher*. However, it is generally understood to simply be nano-scale polycrystalline structures. (*See, e.g.*, Hollister, P., et al., Nanocrystalline Materials, Technology White Papers nr. 4, Cientifica, Oct. 2003, nanotechweb.org/dl/wp/nanocrystalline_materials_WP.pdf, a copy of which is attached as Exhibit A). The term "monocrystalline" is also undefined in *Whitcher*. However, that term is generally understood to mean "formed of a single crystal-unit, and so all elements have identical crystallographic orientation of c- and a-axes and overgrow as one unit." (*See*, <www.nhm.ac.uk/hosted_sites/ina/terminology/7crystallography.htm>.)

Paragraph 0028 of *Whitcher* states in pertinent part "By using vapor deposition techniques for the formation of medical devices, the composition, thickness, surface roughness, and microstructure of devices formed in accordance with the present invention are accurately and precisely controlled." This paragraph is merely a statement of objectives and does not in any manner expressly or implicitly teach what aspects of the

[1] Online website <www.dictionary.com> defines the term "amorphous" as "4.Chemistry. not crystalline."

microstructure may be controlled, and thus fails to specifically teach that precipitates may be controlled.

Paragraph 0038 of *Whitcher* states in pertinent part: "The removal of impurities and the filtering of particular isotopes are useful in the present invention. The crystalline structure of the metallic medical article may be affected by impurities. Single crystal or monocrystalline materials are more easily formed when levels of impurities are minimized." Again this paragraph is devoid of any teaching that the vacuum deposition process may be controlled in such a manner as to minimize intra and intergranular precipitate formation and deposit a crystalline film. Monocrystalline (a/k/a single crystal) materials as taught by *Whitcher* as drawn filaments and are not, therefore, vacuum deposited onto a cylindrical substrate to form a tubular film structure.

Paragraph 0042 of *Whitcher* provides in pertinent part: "A medical device with a nanocrystalline structure is useful because of its enhanced mechanical properties, for instance fatigue resistance and corrosion resistance. A nanocrystalline structure in a biocompatible material with a grain size ranging from about 1 to 500 nanometers is useful as a medical device. Also useful is a biocompatible material with a grain size of about 1 to 100 nanometers. Furthermore, a nanocrystalline structure in a biocompatible material with a grain size of about 1 to 50 nanometers is useful as a medical device. Moreover, a biocompatible material with a grain size of about 1 to 10 nanometers is also useful as a medical." This teaching merely suggests that nano-scale crystal structures are desirable to enhance mechanical properties of the medical device. No teaching as to how the nanocrystalline structure is formed is found in this paragraph.

Paragraph 0043 of *Whitcher*, however, offers the express teaching of how the nanocrystalline structure is formed, wherein it is stated:

> Such nanocrystalline structures can be formed by depositing an amorphous layer of desired material onto a substrate or target. The above-described aging techniques can be used to form nanometer sized crystals. [Referring to Paragraph 0041]. Furthermore, the orientation of the nanometer sized grains can be controlled to yield a orderly grain structure with substantially similar crystal orientation. A useful method for forming such structures is through

> epitaxy where desired material is deposited onto a substrate having a crystalline structure, such as an orientated, nanocrystalline structure, and the deposited material forms a crystalline structure similar to that of the substrate. [Emphasis added].

It is manifestly and unequivocally clear that *Whitcher* teaches depositing a material onto a substrate **in its amorphous state** and after deposition treating or aging the amorphous structure (as expressly taught in Paragraph [0041]) to form either a monocrystalline or nanocrystalline structure. This is without question different and distinct from the presently claimed invention wherein a crystalline film is vacuum deposited onto the substrate under conditions which minimize precipitate formation.

The Examiner goes to great lengths, and without any citation to any references in the art to support her arguments to allege 1) that "granular precipitates are an element of a materials microstructure;" 2) that "inherently the precipitates are controlled, because Whitcher discloses *selection* of a process *condition;*" and 3) that the "amount and size of granular precipitates is dependent upon temp, pressure and rate." It is well settled that an unsupported assertion or conclusion by the Examiner is insufficient basis for rejecting a claim.

Whitcher does not disclose, expressly or implicitly, that vacuum deposition may be controlled to minimize formation of precipitates in the as-deposited crystalline film. In fact, the word "precipitate" does not even appear anywhere in *Whitcher*.

Contrary to the Examiner's assertion, Ferguson Beauregard/Logic Controls, Div. of Dover Resources Inc. v. Mega Systems LLC, 350 F.3d 1327 (Fed. Cir. 2003), does not hold that "selected to minimize" is analogous to "preselected or predetermined", as is alleged by the Examiner. In that case, the Federal Circuit merely held that "the ordinary meaning of 'predetermine' is 'to determine beforehand.' " *See id.* at 1340. There was no reference whatsoever in Ferguson Beauregard to the phrase "selected to minimize." Accordingly, Applicant submits that the Federal Circuit's holding with regard to the term "predetermine" is not germane to the language of the pending claims. Applicant submits, therefore, that the Examiner's characterization of Ferguson Beauregard misapplies the Federal Circuit's actual holding in that case.

For reasons submitted in the Non-Final Office Action of February 24, 2006, Applicant submits that the concept of controlling aspects of the microstructure of a deposited metal is different from the concept of minimizing precipitates in a deposited metal film. As widely known to those skilled in the metallurgical arts, the term "precipitate[2]" is different from the term "microstructure[3]" and different from the term "impurity[4]." In the metallurgical arts as they pertain to fabrication of biomaterials, and with particular reference to nickel-titanium shape memory alloys, precipitates are reaction products formed from a solid solution under increased thermal conditions which drive the precipitate from solution, resulting in formation of the reaction products outside the solid solution, *i.e.*, the metal crystalline structure. An excellent monograph on precipitation reactions in nickel-titanium binary shape memory alloy systems is found at Pelton, A.R., et al., Optimisation of processing and properties of medical grade Nitinol Wire, *Min Invas Ther & Allied Techno.*, 2000: 9(1) 107–118, a copy of which is attached as Exhibit B.

Thus, a "precipitate" is not an "impurity." Rather, it is a reaction product from the solid metal solution. Conversely, an "impurity" is not a "precipitate". Indeed, on paragraph 37, *Whitcher* clearly notes that "other impurities, such as oxygen, that may be contained in the elemental ingot may be filtered away from the substrate with this method" [Emphasis added]. Based on Applicant's meticulous reading, there is no description whatsoever in *Whitcher* indicating that the "impurities" described in *Whitcher* and referenced by the Examiner, actually refer to precipitates.

Furthermore, even assuming *arguendo* that *Whitcher's* teaching of controlling microstructure of the deposited metal is in some manner analogous to Applicant's teaching of minimizing precipitate formation of a deposited metal -- a position that Applicant strongly opposes --, the Examiner's anticipation rejection would still be

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[2] Online website <www.dictionary.com> defines the term precipitate as "a substance precipitated from a solution" and "to separate (a substance) in solid form from a solution, as by means of a reagent."

[3] Online website <www.dictionary.com> defines the term microstructure as "the structure of a metal or alloy as observed, after etching and polishing, under a high degree of magnification."

[4] Online website <www.dictionary.com> defines the term impurity as "the quality or state of being impure."

improper because *Whitcher* does not qualify as an enabling prior art reference with regard to Applicant's pending claims. Courts have consistently held that for a prior art reference to anticipate a claimed invention, the prior art reference must be enabling. *See Amgen Inc. v. Hoechst Marion Roussel*, Inc. 314 F.3d 1313, 1354 (Fed. Cir. 2003) (stating that "a claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosure cited as prior art are not enabled ... a non-enabled disclosure cannot be anticipatory (because it is not truly prior art) if the disclosure fails to 'enable one of skill in the art' to reduce the disclosed invention to practice' " and quoting from *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1962)).

Moreover, according to the Federal Circuit, "[t]o serve as an anticipating reference, the reference must enable that which it is asserted to anticipate" [Emphasis added]. *Elan Pharm., Inc. v. Mayo Found. for Med. Educ. And Research.* 345 F.3d 1051, 1054 (Fed. Cir. 2003). In other words, in order "[t]o anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter" [Emphasis added]. *PPG Indus. V. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

In the pending matter, *Whitcher* does not disclose precipitates or precipitate formation, let alone enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize formation of precipitates, as recited in independent claims 39, 47, and 67. Simply put, Applicant submits that *Whitcher's* brief mention of controlling the microstructure of a vacuum deposited metal would not enable those skilled in the art to conduct vacuum deposition under process conditions selected to minimize precipitate formation.

Thus, for the reasons stated above, Applicant submits that pending claims 39-53 and 67-74 are distinguished from the prior art cited and of record.

SUMMARY

The Examiner's rejections of claims 39-53 and 67-74 have been obviated by the above remarks. Accordingly, Applicant submits that the pending claims are patentably distinct from and over the art cited and of record. Favorable reconsideration of the rejection of the pending claims is solicited.

Any amendments made during the prosecution of this application are intended solely to expedite prosecution of the application and are not to be interpreted as acknowledgement of the validity of any rejection raised earlier in prosecution, nor as acknowledgement that any citation made against the application is material to the patentability of the application prior to amendment.

This Paper is being concurrently filed with an Amendment Transmittal, which includes a fee calculation sheet and any applicable requests for Extension of Time. Other than those stated in the Amendment Transmittal, no additional fees are believed necessitated by the filing of this Paper. Should any such additional fees be required, the Director is hereby authorized to deduct them from Deposit Account No. 18-2000, of which the undersigned is an authorized signatory.

Should the Examiner believe that there are any outstanding matters capable of resolution by a telephone interview, the Examiner is encouraged to telephone the undersigned attorney of record.

Respectfully submitted

Paul J. Lee
Reg. No. 52,420

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ROSENBAUM & ASSOCIATES, P.C.
650 Dundee Road
Suite #380
Northbrook, Illinois 60062
Direct Tel. (847) 770-6016
Fax. (847) 770-6006